UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,781	09/24/2003	Juha Apajalahti	79428	6390

22242 7590 09/12/2005

FITCH EVEN TABIN AND FLANNERY
120 SOUTH LA SALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,781	APAJALAHTI ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 24 September 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/251,503.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-11 are under consideration in this Office Action.

2. The disclosure is objected to because of the following informality: in the specification there is no statement that indicates that the instant application is a continuation of Serial No. 10/251,503 (US Patent 6,638,746, which is a continuation of Serial No. 09/242,499 (abandoned), which is the US National Stage filing of PCT Application No. PCT/EP97/04385. Furthermore, the specification does not state that the instant application claims foreign priority under 35 U.S.C. 119(a)-(d) to foreign patent application 9616957.8 filed in the United Kingdom on 08/13/1996.

This information should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 6-8 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claims, as written, encompass naturally whole organisms including humans, animals, plants and transgenic humans, animals, plants, all of which are non-statutory subject matter. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. The clams should be amended to recite the phrase "an isolated eukaryotic host cell".

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly

claiming the subject matter which the applicant regards as his invention.

6. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

The claims are vague and indefinite for reciting PCR amplification conditions, which are not hybridization conditions. Furthermore, the PCR amplification conditions require the correct primers having specific nucleotide sequences. Thus, the metes and bounds of the invention are not known since it is unclear how any nucleic acid can hybridize to SEQ ID NO: 1 under the recited PCR amplification conditions. Appropriate correction is requested.

The claims will only be examined to the extent of a nucleic acid that hybridizes to SEQ ID NO: 1 under the recited conditions of 6xSSC, 0.6% SDS, and 50°C.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid of SEQ ID NO: 1, an isolated host cell transformed with a nucleic acid of SEQ ID NO: 1, a method for making a phytase comprising transforming an isolated host cell with SEQ ID NO: 1; does not reasonably provide enablement for any nucleic acid that hybridizes to SEQ ID NO: 1 under the recited hybridization conditions (6xSSC, 0.6% SDS, 50°C), any eukaryotic host cell, eukaryotic organism, plant, transgenic eukaryotic organism, or transgenic plant transformed with any nucleic acid that hybridizes to SEQ ID NO: 1 under the recited hybridization conditions, and any method for making a phytase comprising transforming any host cell with any nucleic acid that hybridizes to SEQ ID NO: 1 under the recited hybridization conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are

summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any nucleic acid that hybridizes to SEQ ID NO: 1 under the recited hybridization conditions of 6xSSC, 0.6% SDS, and 50°C.

While the specification provides guidance for SEQ ID NO: 1, the specification does not provide guidance, prediction, and working examples for making any nucleic acid that hybridizes to SEQ ID NO: 1 under the recited hybridization conditions.

Thus, an undue amount of trial and error experimentation must be preformed to make the claimed nucleic acid. Such experimentation entails searching and screening for every nucleic acid that hybridizes to SEQ ID NO: 1 under the recited hybridization conditions which will encode a functional phytase. Such trial and error searching and screening is outsider the realm of routine experimentation. General teachings from the specification using enzyme assays are not guidance for making the invention. In view of the above considerations, the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make any nucleic acid that hybridizes to SEQ ID NO: 1 under the recited conditions.

Furthermore, the nature and breadth of the claims 7 and 8 encompass any eukaryotic host cell, organism, or transgenic organism transformed with a nucleic acid that hybridizes to SEQ ID NO: 1 under the recited hybridization conditions.

While the specification provides guidance for transforming isolated *E.coli* host cells with SEQ ID NO: 1, the specification does not provide guidance, prediction, and working examples for making any eukaryotic host cell, eukaryotic organism, plant, transgenic eukaryotic organism, or transgenic plant transformed with any nucleic acid that hybridizes to SEQ ID NO: 1 under the recited hybridization conditions. Thus, an undue amount of trial and error experimentation must be preformed to make the claimed invention.

In view of the above considerations, the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use any eukaryotic host cell, eukaryotic organism, plant, transgenic eukaryotic organism, or transgenic plant transformed with any nucleic acid that hybridizes to SEQ ID NO: 1 under the recited conditions.

9. Claims 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it

is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claim encompasses any method for producing a nucleic acid which encodes a phytase by hybridizing any probe that comprises any nucleic acid encoding any phytase. While the specification provides guidance for SEQ ID NO: 1, the specification does not provide guidance, prediction, and working examples for making any probe of any nucleic acid sequence that will hybridize to any nucleic acid encoding any phytase and the specific hybridization conditions that will result in the probe specifically hybridizing to a nucleic acid encoding a phytase. Thus, an undue amount of trial and error experimentation must be preformed to make the claimed probe.

Such experimentation entails searching and screening for every nucleic acid probe that will specifically hybridize to a nucleic acid that encodes any phytase and any hybridization condition that will result in the probe specifically hybridizing to a nucleic acid encoding a phytase. Such trial and error searching and screening is outsider the realm of routine experimentation. General teachings from the specification using enzyme assays are not guidance for making the invention. In view of the above considerations, the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to

overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,638,746. Although the conflicting claims are not identical, they are not patentably distinct from each other since the claims of the instant application are anticipated by claims 1-11 of U.S. Patent No. 6,638,746.

The claims of the instant application encompasses any isolated nucleic acid which hybridizes to SEQ ID NO: 1 under the recited conditions and encodes any phytase, vectors comprising said nucleic acid, host cells transformed with said nucleic acid, methods for producing a phytase using said host cells, and method for production of said nucleic acid using probes.

However, U.S. Patent No. 6,638,746 teaches a nucleic acid that is 100% identical to SEQ ID NO:1 of the instant invention and encodes a phytase (see enclosed alignment), vectors comprising said nucleic acid, host cells transformed with said nucleic acid, methods for producing a phytase using said host cells, and method for production of said nucleic acid using probes. Thus, claims 1-11 of U.S. Patent No. 6,638,746 anticipate claims 1-11 of the instant application.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

PONNATHAPU MURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600